5. 510(k) Summary

JUN 14 2013

Date Prepared: March 15, 2012

Device Trade Name: Modulap Loop

Common Name: Unipolar endoscopic coagulator-cutter

Submitter:
ATC Technologies Inc.
30B Upton Drive,
Wilmington, MA 01887

Contact Person:
John Gillespie (consultant)
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Classification: Coagulator-Cutter, Endoscopic, Unipolar (and accessories) 21 CFR 884.4160, Product code KNF, Class II

Intended Use: The Modulap Loop is intended for the amputation of the uterus during laparoscopic supracervical hysterectomy and for resection of pedunculated subserosal (abdominal) myomas.

It is not intended for use in hysteroscopy or for contraceptive coagulation of the fallopian tubes.

Description of Device

The Modulap Loop is a 5 mm laparoscopic instrument. It consists of a standard insulated monopolar electrosurgical probe, with a flexible wire loop as its distal tip, and a sliding sheath constructed of insulating material. The wire loop is insulated except for a central approximately 1 inch cutting area. The device is a single-use sterile, disposable device. It is compatible with standard electrosurgical generators, and associated cables.

Summary of Technological Characteristics vs. Predicate

The Modulap Loop and the Predicate device (Lina Gold Loop, K070315) are both Monopolar electrosurgical electrode with loop style tip and sliding sheath; sized to pass through 5 mm laparoscopic trocar; and compatible with standard electrosurgical generators. Their indications for use are equivalent, and other technological characteristics such as design, materials, performance, anatomical sites, energy used, human factors, biocompatibility, sterility, electrical safety, mechanical safety and standards met are the same or equivalent.

Test Data

Testing including performance, reliability, materials property testing, biocompatibility, packaging validation and electrical safety testing was performed which supports that the Modulap Loop is equivalent to the predicate with regard to safety and effectiveness.

Substantial Equivalence

Based on the Indication for Use, technological characteristics, performance testing, and comparison to its predicate device we conclude that the Modulap Loop has been shown to be substantially equivalent to a legally marketed predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 14, 2013

ATC Technologies, Inc.
% Mr. John Gillespie
Consultant
Clover Medical
79 Haven Street
DOVER MA 02030

Re: K121343
Trade/Device Name: Modulap Loop
Regulation Number: 21 CFR§ 884.4160
Regulation Name: Unipolar endoscopic coagulator-cutter and accessories
Regulatory Class: II
Product Code: KNF
Dated: May 17, 2013
Received: June 7, 2013

Dear Mr. Gillespie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K121343

Device Name: Modulap Loop

Indications for Use:

The Modulap Loop is intended for monopolar electrosurgical coagulation/cutting during laparoscopic surgery. It is indicated for the amputation of the uterus during supracervical hysterectomy and for resection of pedunculated subserosal (abdominal) myomas.

It is not intended for use in hysteroscopy or for contraceptive coagulation of the fallopian tubes.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

K121343